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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,644	09/18/2001	Eric Silverberg	1893	1184

7590

05/15/2006

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EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 05/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/955,644

Applicant(s)

SILVERBERG ET AL.

Examiner

Isis Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/27/05; 2/23/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicants' request for RCE, amendment, and IDS, all filed 12/27/2005; and IDS, declaration and supplemental amendment, all filed 02/23/2006.

Claims 1-20 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/27/2005 has been entered.

Terminal Disclaimer

2. The terminal disclaimer filed on 02/23/2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,077,527 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-6, 8-17 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/08229 ('229).

WO '229 disclosed pressure sensitive adhesive composition comprising acrylic polymer comprising 40-95% of one or more A monomers selected from the group consisting of alkyl acrylates and/or alkyl methacrylates, and up to 60% of one or more B monomers (page 2, lines 5-23). Preferred A monomers include 2-ethylhexyl acrylate, n-butyl acrylate, and methyl methacrylate (page 4, lines 3-14). B monomers include substituted acrylamide, methacrylonitrile, and vinyl acetate (page 4, lines 25-27; page 5, lines 7-12). The polymer composition is used to form matrices for transdermal drug delivery device (page 2, lines 5-13; page 3, lines 29-30). The transdermal device comprises a backing layer, a matrix layer comprising the polymer composition and a therapeutic active agent, and a release liner (page 2, line 6; page 13, line 22; page 14,

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lines 16-17, 26). WO '229 further contemplates various drugs for delivery by the device including analgesics such as fentanyl (page 12, line 28). The pressure sensitive adhesive has a glass transition temperature of -10^0 C (page 11, lines 4-5). The reference does not teach any cross-linking agent in the polymer composition or any functional groups containing reactive hydrogen.

5. Claims 1-11, and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,077,527 ('527).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US '527 disclosed a pressure sensitive adhesive composition for use in transdermal drug delivery devices comprising at least 40% by weight of alkyl acrylate including n-butyl and 2-ethylhexyl acrylate, and 10-60% by weight of substituted acrylamide or methacrylamide including t-octyl acrylamide (abstract; col.2, lines 45-60; col.3, lines 60-67; col.4, lines 8-16). The Tg of the composition is calculated by the examiner to be below 10^0 C. The reference does not disclose any reactive groups after the cross-linking.

Response to Arguments

6. Applicant's arguments filed 02/23/2006 have been fully considered but they are not persuasive. Applicants traverse the anticipatory rejection of claims 1-7 over US '527 by arguing that the composition disclosed by US '527 must contain crosslinker and must contain a compound comprising a reactive hydrogen. There is always functional groups not consumed by the cross linker.

In response to applicants' argument, the examiner position is that US '527 does not disclose the presence of reactive sites after polymerization, i.e. no post-polymerization chemical crosslinker. The reference disclosed the monomers containing reactive hydrogen as an optional ingredient. The expression "comprising " of the claim language permits the presence of other ingredients and does not preclude the presence of other ingredients, active or inactive, even in major amounts. See *Moleculon Research Corporation v CBS, Inc.* 229 USPQ 805, *In re Baxter* 210 USPQ 795, 803. Therefore, the claim language permits the presence of polymers containing functional groups. The disclosed examples and preferred embodiment do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 7 and 18-10 are rejected under 35 U.S.C. 103(a) as being obvious over WO 96/08229 ('229) by itself or in view of US 6,077,527 ('527).

The applied reference US '527 has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the

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application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

The teachings of WO '229 and US '527 are discussed above.

However, WO '229 does not teach the specific t-octyl acrylamide claimed in claims 7 and 19, or the combination of 2-ethylhexyl acrylate and methyl acrylate as claimed in claim 18.

The art recognized the suitability of N-substituted methacrylamide monomer in pressure sensitive adhesive used in transdermal devices, therefore, the specific species t-octyl acrylamide does not impart patentability to the claims, absent evidence to the contrary. The art recognized combination of the acrylate monomers in adhesive compositions, therefore, the combination claimed by applicants does not impart patentability to the claims, absent evidence to the contrary.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver the adhesive composition comprising alkyl acrylate monomer and non-cyclic nitrogen containing monomer as disclosed by WO '229, and select t-octyl acrylamide disclosed by US '527 as the non-cyclic nitrogen containing monomer, motivated by the teaching of US '527 that the adhesive composition having this monomer maintains appropriate pressure sensitive properties over time, with

reasonable expectation of having an adhesive composition to be used in transdermal drug delivery matrices that maintain it appropriate pressure sensitive properties over time to allow drug delivery for the desired period of time to the patients.

Response to Amendment

10. The declaration filed on 02/23/2006 under 37 CFR 1.131 has been considered but is ineffective to overcome the U.S.C. 102 (e) rejection over US 6,077,527 reference. The evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the US 6,077,527 reference. The submitted document showing the invention disclosure record of the present invention was prepared and executed prior to June 20, 2000, which is the publication date of US 6,077,527 which is later than the earliest effective filing date of the present application, September 19, 2000. However, US 6,077,527 is entitled to priority date of October 28, 1997 which is the effective filing date of US 6,077,527. Therefore, the declaration under 37 C.F.R. 1.131 is insufficient to overcome the U.S.C. 102 (e) rejection over US 6,077,527 reference.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

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number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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ISIS GHALI
PATENT EXAMINER